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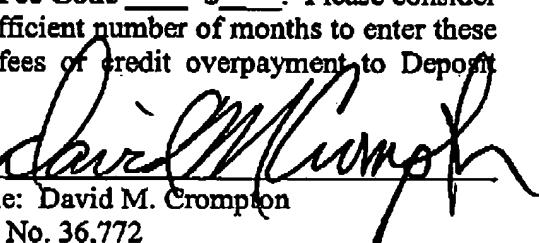
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Applicant: Jill McFadden et al.
 Serial No.: 09/097,023
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P A T E N T

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Jill McFadden et al. Confirmation No.: 2472
Serial No.: 09/097,023 Examiner: M. Hayes
Filing Date: June 12, 1998 Group Art Unit: 3763
Docket No.: 1001.1566101 Customer No.: 28075
For: CATHETER WITH KNIT SECTION

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September 20, 2005

Date

Dear Sir:

Pursuant to 37 C.F.R. §41.41, Appellants hereby submit this Reply Brief in response to
the Examiner's Answer mailed July 26, 2005. Remarks begin on page 2.

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REMARKS

Removal of Grouping of Claims Requirement

With respect to grouping of claims, Appellants respectfully point out that, by virtue of amendments to 37 C.F.R. made effective September 13, 2004, 37 C.F.R. §1.192(c)(7) has been removed. As noted in the Federal Register, in the comments accompanying the final rule, "The grouping of claims requirement set forth in former rule 192(c)(7) is removed." (Federal Register, Vol. 69, No. 155, at p. 49,962). Thus, Appellants are no longer required to include a statement in the Appeal Brief as to whether or not the claims stand or fall together. Regulations governing the Appeal process are now provided at 37 C.F.R. Section 41. Since the claims were argued separately, Appellants maintain the position that the claims do not stand or fall together. Thus, the Appeal Brief was correct.

Errors in the Examiner's Reliance of JP 05-220225

1. The Examiner cannot read the term "knit" in a vacuum.

The Examiner suggests JP 05-220225 anticipates the previously stated rejected claims of the present invention. In upholding the rejection, the Examiner states he is relying on the "plain language" of the term "knit" as it is used throughout the machine translations of the document, without taking into consideration what is disclosed in the accompanying drawings. See Examiner's Answer, page 5. The Examiner's sole reliance on the word "knit", without construing the term in view of intrinsic evidence provided in the document or taking into consideration any of the structural differences shown in the drawings in upholding the rejection are without merit. When an extrinsic reference source, such as a dictionary, evidences more than one definition for a term, it is imperative to consult any intrinsic evidence in the document to discern which of the different possible definitions is most consistent with the use of the term in the document.

The machine translation provided by Appellants, which is provided in Appendix C of the Appeal Brief, describes the reinforcement layer 35 as being continuously formed by turns such that the first wire layer 35A has a pitch P1 of 1 mm and the second wire layer 35B has a pitch P2 of 10 mm. See Appendix C, paragraph 19. Alternatively, the machine translation provided by the Examiner describes the reinforcing layer 35 as including a dense mesh wire layer 35A having a pitch P1 of 1 mm and a rough mesh wire layer 35B having a pitch P2 of 10 mm formed

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alternately. See Appendix B, paragraph 19. In view of the disparity of the two translations, harmonization of the two documents must be undertaken.

Appellants disagree with the Examiner's assertion that Appellants have "forced the wording to fit an unreasonable interpretation" of the document. See Examiner's Answer, page 6. Indeed, the interpretation of the document given by Appellants is not only reasonable, but it is one that would be reached by an individual of ordinary skill in the art. Braided or woven members typically include a plurality of filaments extending in opposing helical directions and positioned either above or below an intersecting filament at cross-over points throughout their length. Thus, the braids are formed by alternately placing filaments over and under intersecting filaments to create the braid.

Furthermore, consistent with the teachings of JP 05-0220225, braided or woven members are typically described by the pitch of their filaments. "Pitch" is a term commonly attributed to the distance between adjacent windings of a filament. Indeed, that is how the term is used in JP 05-220225. As shown in Figure 5, P1 is the distance between adjacent windings in the tightly braided section 35A, and P2 is the distance between adjacent windings in the loosely braided section 35B. Indeed, a section having a pitch of 1 mm would create a relatively dense mesh as individual adjacent windings would be positioned 1 mm apart. A section having a pitch of 10 mm would create a relatively loose mesh as individual adjacent windings would be positioned 10 mm apart. This can be seen from Figure 5, which shows the helically extending filaments spaced farther apart in the central portion 35B than in the end sections 35A. Thus, one of ordinary skill in the art, after reading this description, would conclude that the reinforcement layer 35, described as being formed by turns or alternately and having a specified pitch, is in actuality a woven or braided member.

Even though the two translations use different terminology to describe the formation of the reinforcement layer 35, the teachings of the translations must be harmonized for all that they teach, and not gleaned for only those portions deemed favorable to a preferred position. To the contrary, the Examiner has attempted to neglect portions of the document which clearly do not support his position. A term cannot be read in a vacuum, but must be construed in view of the accompanying description. Thus, a term must be given the meaning attributed to it by the description, regardless of alternate definitions it may have. One may not disregard the part of the description which expressly identifies the pitch of the relevant portions of the reinforcement

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member 35. When read in view of the drawings and accompanying description, it is clear that the reinforcement member taught in JP 05-220225 is a braided or woven member, and not a knitted member in the sense that the term is used to describe the currently claimed invention.

2. The term "knitted" does not inherently mean interlocking up and down loops.

The Examiner takes the position that "knitted" inherently means interlocking up and down loops. See Examiner's Answer, page 5. Contrary to the Examiner's assertion, Appellants have never taken this position. The Examiner has identified specific instances in the record where Appellants have supported their current position that the term "knitted" as used in the current application describes a structure having interlocking up loops and down loops. The Examiner attempts to take these statements found in the record and construe them out of context. However, these statements only embolden the position maintained by Appellants.

Regarding the first incidence quoted by the Examiner, Appellants were responding to the then pending rejection in view of Cornelius et al., U.S. Patent No. 5,338,295, in which the Examiner took the position that a clothing weave was equivalent to a knitted member. See Office Action mailed May 9, 2001, paragraph 3. In the Response that followed, Appellants refuted the Examiner's position. The full text of the first incidence refuting the rejection which was quoted by the Examiner states:

The Office Action contends that "a weaved braid is the same as a knit." However, by the Examiner's own description, a weave is defined "to form by interlacing strands" and a knit is defined "to form by interlacing in a series of connected loops with needles." (Office Action Paper No. 18, p. 2-3.) Interlacing strands cannot be the equivalent of interlacing in a series of connected loops because in a knit, individually formed loops are connected together (see Specification, p. 8, lines 8-9 & Fig. 4), whereas in a weave, no such loops exist. Therefore, a knit *cannot* be the same as a "clothing weave."

See Amendment mailed July 5, 2001, page 2.

In responding to this argument in the next Office Action, the Examiner stated:

Applicant's entire argument rests on the difference between a "weave" and a "knit". Applicant primarily argues that, "Interlacing strands cannot be the equivalent of interlacing in a series of connected loops because in a knit, individually formed loops are connected together....whereas in a weave, no such loops exist." While the Examiner still contends that given the multiple definitions given to the word "knit" that the interpretation of a braid or weave may still read on a knitted structure one might still focus on the series of connected loops.

See Office Action mailed September 25, 2001, paragraph 7.

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Regarding the second occurrence quoted by the Examiner, in the following Response Appellants renewed their assertion that the term "knitted" as used in the current application describes a structure having interlocking up loops and down loops. The full text of the second incidence refuting the rejection which was quoted by the Examiner states:

The impropriety of equating woven and knit tubular members is further borne out in the differences in the definition provided in Webster's Ninth New Collegiate Dictionary. Woven is merely defined as interlacing strands, while knit is defined as interlacing in a series of connected loops with needles. The Examiner seems to recognize that there is a difference in the definitions when discussing his response to Applicants' prior arguments. The Examiner asserts that there are multiple definitions given to the word "knit". However, we are presently dealing with only one definition which Applicants accept from the Webster's Ninth New Collegiate Dictionary. The Examiner attempts to assert that the Cornelius et al. disclosure includes a loop structure that occurs within a given strand within the weave by discussing the way in which a single strand loops around the tubular member. However, the strands merely each define a helical pattern as they circle around the tubular member. This is not the definition of a knit tubular member as disclosed in Applicants' specification. In Applicants' specification, it is clear that the term "knit" refers to the disclosed structure when looking at the surface of the member which includes the up loops and down loops created in the knitting process. Cornelius et al. do not disclose or teach such structure.

See Amendment mailed January 25, 2002, pages 3-4.

Thus, when the entire context of the exchanged remarks is presented, it becomes apparent that Appellants have never taken the position that "knitted" inherently means interlocking up and down loops. To the contrary, Appellants have maintained that the term "knit" has multiple definitions and the definition attributed to the knitted tubular member disclosed in Appellants' specification and accepted throughout prosecution is a member formed by a plurality of interlocking up loops and down loops.

Appellants have repeatedly attempted to distinguish the structure of the knit as used in the current application from a weave. Through an examination of the exchanged remarks reproduced above, it is clear that previously the Examiner has taken the position that a knit is equivalent to a weave. Indeed, the Examiner is contradicting himself when he states, "The examiner takes the position that 'knitted' inherently means interlocking up and down loops." See Examiner's Answer, page 5. As shown above, at an earlier stage in the prosecution of the application, the Examiner attempted to connote a knit with a weave (i.e., a structure not having

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interlocking up and down loops). Furthermore, the Examiner seems to agree that the term "knit" possesses multiple definitions, and has been used to describe dissimilar structures, some of which do not include interlocking up and down loops. Therefore, the Examiner, himself, must concur that "knitted" does not inherently (i.e., in all instances) mean interlocking up and down loops.

3. The structural arrangement of the reinforcing member taught in JP 05-220225 would not inherently result in being generally not radially expandable.

Appellants reject the Examiner's argument that the structural limitation of being generally not radially expandable is inherently found in JP 05-220225. The Examiner's position that "the prior art shows a knitted member generally not radially expandable because there is resistant [sic] to expansion due to the interlocking loops" is erroneous for at least two reasons.

First, the Examiner's position is premised on an erroneous assumption that JP 05-220225 teaches interlocking up loops and down loops. Appellants' position that JP 05-220225 indeed does not teach interlocking up loops and down loops has been described in great detail above, in Appellants' Appeal Brief, and throughout prosecution. Therefore, additional comment regarding this erroneous assumption is deemed unnecessary. Attention may be directed to these earlier remarks if further consideration is warranted.

Second, the Examiner's position is premised on an erroneous inherency argument. As detailed in Appellants' Appeal Brief, "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic." M.P.E.P. §2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis in original). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference.'" M.P.E.P. §2112, quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added). In other words, the inherent property or characteristic must be present in all occurrences. Cook, U.S. Patent No. 4,637,396, provides one occurrence in which a knitted member is radially expandable. The knitted middle layer 23 taught in Cook, U.S. Patent No. 4,637,396 includes an elastic ply 39B, such as Spandex, which allows the knitted middle layer 23 to have desired expansion and contraction characteristics. See Cook, column 3, lines 10-22. This exemplary instance establishes an occurrence of when a knitted member is radially expandable. Therefore, a knitted member is not necessarily not radially expandable as the

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Examiner erroneously concludes in asserting that the structural limitation is inherent in the prior art. Therefore, the inherency argument suggested by the Examiner is without merit.

Additionally, the Examiner asserts the densely knitted member has "great torsional rigidity", and this "structural arrangement" would inherently result in being generally not radially expandable. See Examiner's Answer, page 6. This is obviously an untrue statement. The structural limitation of "generally not radially expandable" is independent of the structural limitation of "great torsional rigidity". The ability of the densely braided portion of the reinforcement member 35 taught in JP 05-220225 to have higher torsional rigidity than the more loosely braided portion is due to the variation in density of the filaments forming the braided portions. The pitch of the filaments as described in JP 05-220225 corresponds to the density of the filaments. The pitch of the more densely braided portion 35A is 1 mm and the pitch of the more loosely braided portion 35B is 10 mm. Thus, adjacent filaments are more tightly arranged in the dense portion 35A, and adjacent filaments are more sparsely arranged in the loose portion 35B. This can be visualized from Figure 5. The more tightly arranged filaments provide greater torsional rigidity than the more loosely arranged filaments.

To the contrary, the limitation of being generally not radially expandable is not necessarily dictated by how densely or loosely filaments are arranged, but may be controlled by factors such as the elasticity of the filaments, the ability of individual filaments to move relative to one another, the strength of adhesion of the filaments to a substrate, the elongation of the filaments, etc. None of which are described in JP 05-220225. Thus, the structural limitation of "generally not radially expandable" is independent of the structural limitation of "great torsional rigidity" and not anticipated by JP 05-220225.

For at least the reasons presented above, as well as the reasons laid out in the Appeal Brief, Appellants maintain the position that JP 05-220225 fails to anticipate the rejected claims.

Errors in the Examiner's Reliance on Leoni

In what appears to be a concession by the Examiner that the reinforcing net taught in Leoni is made of a plurality of monofilaments extending helically around the balloon section, wherein the monofilaments are movable with respect to each other at the crossover points between monofilaments, the Examiner suggests that Appellants have not recited a limitation that there is no movement at crossover points in the claimed knitted structure. No such recitation is

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deemed necessary or appropriate. Appellants have affirmatively recited that the knitted tubular member is formed from a plurality of interlocking up loops and down loops and is generally not radially expandable. This is clearly a dissimilar structure to that taught in Leoni.

The crossover points, as shown in Figure 3 of Leoni, are points where converging monofilaments extend over or under one another, but continue in the same direction. The monofilaments never change direction, and thus never create interlocking up loops and down loops. As evidenced in the limitations recited in claim 6 of Leoni, the crossover points are equally applicable to what Leoni considers to be a knitted member, as well as a braided member.

To the contrary, a knitted tubular member as intended in the current application and adequately claimed is formed from a plurality of interlocking up loops and down loops. A visual understanding of this limitation is shown in Figure 4 of the current application. The individual filaments forming the claimed knitted structure repeatedly change directions in order to form the interlocking up loops and down loops. This is clearly a dissimilar structure to that disclosed and claimed in Leoni. Even though each member is described as knitted, identically named parts in a prior art reference must have the same structure or otherwise satisfy the claim limitations of the claimed element in order to anticipate. See *Applied Medical Resources Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 47 USPQ2d 1289 (Fed Cir. 1998). It is evident that Leoni describes a dissimilar structure than that currently claimed.

Additionally, the Examiner asserts that Leoni teaches a non-expandable section, and that this non-expandable section meets the claim limitation that the knitted tubular member is generally not radially expandable. However, as previously noted, the expandable balloon section (11) has a reinforcement net (2) made of metallic monofilaments surrounding the balloon section (11) and moveable with respect to each other at crossover points (5) to allow expansion of the balloon section (11). Thus, at least the main portion of the reinforcement net overlaying the balloon section is expandable. As this portion of the reinforcement net is expandable, Leoni fails to meet the claim limitation that the knitted tubular member is generally not radially expandable.

Furthermore, the Examiner erroneously maintains the position that interlocking up and down loops are inherently found in a knitted member. However, throughout the prosecution history the Examiner agrees that the term "knit" possesses multiple definitions, and has been used to describe dissimilar structures, some of which do not include interlocking up and down loops. For example, as noted above regarding the quoted exchange between Appellants and the

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Examiner during prosecution, at one point in the prosecution history the Examiner was of the opinion that a clothing weave was equivalent to a knit. Appellants, thereafter adopting one of the several definitions for "knit", further recited in the claims that the structure of the knitted tubular member intended by the current application is formed from a plurality of interlocking up loops and down loops. Thus, "knitted" has clearly been interchangeably used by the Examiner to describe dissimilar structures, some of which do not include interlocking up and down loops. Therefore, the Examiner, himself, must concur that "knitted" does not inherently (i.e., in all instances) mean interlocking up and down loops.

For at least the reasons presented above, as well as the reasons laid out in the Appeal Brief, Appellants maintain the position that Leoni fails to anticipate the rejected claims.

Errors in the Examiner's Reliance on Cook and Cox

As stated in Appellants' Appeal Brief, motivation to combine references must be shown in order to establish a *prima facie* case of obviousness. "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. §2143.01, quoting *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As stated in the Appeal Brief, modifying Cook with the woven support structure suggested in Cox would impart undesired rigidity into the balloon of Cook and prevent desired expansion of the balloon. Likewise, modifying Cox with the expandable knitted member taught in Cook would impart undesired expansion to the adaptor taught in Cox, and not aid in enhancing the radial rigidity of the adaptor that the woven support attempts to accomplish. Thus, replacing the reinforcement member of either device with the reinforcement member of the other device would render the modified device unsatisfactory for its intended purpose. When the proposed modification renders the modified device unsatisfactory for its intended purpose, all other possible rationale for establishing a *prima facie* case of obviousness are irrelevant. Notwithstanding other bases against the establishment of a *prima facie* case presented in the Appeal Brief, the Examiner has failed to overcome this lack of motivation and thus has failed to establish a *prima facie* case of obviousness.

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For at least the reasons presented above, as well as the reasons laid out in the Appeal Brief, Appellants maintain the position that a *prima facie* case of obviousness of the rejected claims has not been established with the combination of Cook and Cox.

Errors in the Examiner's Other Rejections

Appellants maintain the position that a *prima facie* case of obviousness has not been established regarding each of the remaining §103(a) rejections. Appellants refer to the shortcomings of each of the references individually and/or in combination as discussed above, in the Appeal Brief, and throughout prosecution. The proposed combinations of references fail to teach each and every claimed element, lack motivation to combine, and/or fail to generate a reasonable expectation of success. Therefore, a *prima facie* case of obviousness has not been established.

Conclusion

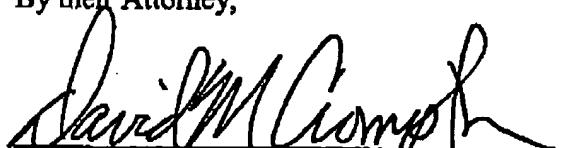
Appellants maintain the position that each of the rejections of claims 1-15, 17-22, 24-42, 44-48, 50, 53-56, 58, 59 and 61-63 under 35 U.S.C. §§102(b), 102(e), and 103(a) should be reversed.

Respectfully submitted,

Jill McFadden et al.

By their Attorney,

Date: 9/20/05



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